REMARKS

The invention as presently claimed relates to assay devices for determining the presence or amount of an analyte of interest in a sample, and kits containing such devices. The devices of the present invention comprise, *inter alia*, the following elements: (i) a reaction chamber comprising an optically detectable label; (ii) a diagnostic lane comprising at least one assay zone configured to bind the analyte of interest, and at least one timing zone; (iii) an optical component configured to detect an optical signal generated from the timing zone and generate an electronic signal in response; and (iv) a signal processor configured to read the electronic signal and determine the progress of the assay and its time of completion.

Claims 27, 28, and 93-128 are pending in the application.

In the Examiner's Answer, the Examiner indicated that claims 97, 98, 105, 106, 119, and 120 would be allowable if rewritten in independent form, including the limitations of the claims from which they depend. By this submission, claims 97, 105, and 119 are amended in accordance with the Examiner's remarks.

Notwithstanding the foregoing, Applicant expressly reserves the right to file subject matter no longer or not yet claimed in one or more applications that may claim priority to the present application.

Applicant requests reconsideration of the claimed invention in view of the foregoing amendments and the following remarks.

1. Anticipation rejection based on Buechler, U.S. Patent 5,458,852

Applicants respectfully traverse the rejection of claims 27, 93, 94, 96, 99-100, 109-116, 118, and 121-126 as allegedly being unpatentable as anticipated by Buechler *et al.*, U.S. Patent No. 5,458,852 ("the '852 patent"). Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of anticipation.

The devices of the present invention comprise, *inter alia*, the following elements: (i) a reaction chamber comprising an optically detectable label; (ii) a diagnostic lane comprising at

least one assay zone configured to bind the analyte of interest, and at least one timing zone; (iii) an optical component configured to detect an optical signal generated from the timing zone and generate an electronic signal in response; and (iv) a signal processor configured to receive said electronic signal and to determine the progress and time of completion of an assay for the analyte of interest from at least one of a rate of change of the amount of the electronic signal and an amount of the electronic signal. *See, e.g.*, claim 27.

The Examiner continues to analyze the '852 patent from a flawed perspective, and indeed, a perspective that was rejected by the BPAI on appeal. Specifically, the Examiner states that the primary '852 patent discloses "a time gate for measuring the reaction in a given period of time." Examiner's Answer, page 5, emphasis added. This interpretation of the time gate disclosed in the '852 patent is not supported by the '852 patent. For example, column 7, lines 41-45 of the '852 patent defines a time gate as follows:

> Time Gate
>
> Referring to FIG. 1a, the time gate 5 holds the reaction mixture in the reaction chamber 4 for a given period of time. The concept of the time gate is that a predominantly aqueous solution cannot pass through a hydrophobic zone until the hydrophobic zone is made hydrophilic.

As is made clear by this definition, the "time gate" of the '852 patent is not involved in *measuring* any reaction, contrary to the Examiner's position.

On page 10 of its Decision on Appeal in the present case, the BPAI made clear that the Examiner's analysis of the time gate disclosed in the '852 patent is incorrect, stating "Buechler's optical component is 'not appropriately configured' (Br. 17), i.e., it is not in the correct position, to detect a signal from the optically detectable label within the time gate. Nor has the Examiner identified any reason that would have prompted one of skill in the art to combine, or configure, Buechler's time gate and optical component in the way the claimed invention does."

Inexplicably, when evaluating this same discussion of the time gate disclosed in the '852 patent, the Examiner refers to it as "a positive control analogous to the independent control described in the present specification. The positive control appears to be designed to independently confirm that the assay reagents have actually passed over the capture zones, i.e., that the assay has run to completion." Examiner's Answer, page 9. This suggestion, however, appears to be directed to the discussion in the Decision on Appeal of a completely different element disclosed in the '852 patent – that of a positive control zone present in a diagnostic lane. See pages 11-12 of the Decision on Appeal.

Applicants respectfully submit that the mere presence of a positive control in an assay device does not indicate that a signal generated therefrom is used to determine the progress and time of completion of an assay for the analyte of interest from at least one of a rate of change of the amount of the electronic signal and an amount of the electronic signal, as required by the present claims. Rather, a "positive control" as that term is used in the art typically ensures that the reagents used in the assay are still active; that is, to detect "false negatives." More specifically, a negative result at the "positive control" invalidates the assay because any negative result for the analyte from such assay cannot be considered accurate. Moreover, the time for an assay to run to completion is not measured by monitoring such a "positive control," but rather is a predetermined set time. This is the principle difference between the present invention and the prior art.

For example, U.S. Patent 5,447,837 issued to Urnovitz discloses a test strip for detecting an analyte. The test strip comprises "an anti-human antibody bound to a second discrete area on the solid support as a positive control." U.S. Patent 5,447,837, column 2, lines 15-21. The test protocol is summarized in Fig. 4, with a negative and positive control used to screen for false positives and negatives, respectively. In Example 5, U.S. Patent 5,447,837 uses such a dipstick test strip which comprises a positive control zone (column 17, lines 50-51). The assay is run using predetermined incubation times, and there is no indication that a signal from the positive

control zone is used to monitor the time of completion of the assay, as required by the present claims.

There is nothing in the cited '852 patent that indicates its positive control is used in any different fashion than that of the positive control in U.S. Patent 5,447,837, discussed above. It is important to note that nothing in the '852 patent explicitly describes the claimed signal processor configured to receive an electronic signal and to determine the progress and time of completion of an assay for the analyte of interest from at least one of a rate of change of the amount of the electronic signal and an amount of the electronic signal. Applicants note that if the Examiner believes that the '852 patent inherently teaches this claim element, it is incumbent upon the Examiner to establish that fact. *See, e.g.*, MPEP §2112 (to establish inherency, the Examiner must establish that the characteristic(s) in question must necessarily be provided by the cited publication). By failing to do so, the Examiner has failed to establish a *prima facie* case of anticipation.

In view of the foregoing, Applicant respectfully submits that no *prima facie* case of anticipation has been established, and requests that the rejection be reconsidered and withdrawn.

2. Obviousness rejection based on Buechler, U.S. Patent 5,458,852

Applicants respectfully traverse the rejection of claims 27, 93, 94, 96, 99-100, 109-116, 118, and 121-126 as allegedly being unpatentable as obvious over Buechler *et al.*, U.S. Patent No. 5,458,852 ("the '852 patent"). Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness.

The entirety of the Examiner's obviousness analysis is that if the '852 patent does not anticipate the claimed invention, "[a]bsent evidence to the contrary the invention is alternatively considered obvious." Examiner's Answer, page 9. Applicants note that it is not the obligation of the applicant to provide evidence disproving obviousness in the absence of a *prima facie* showing. Rather, the Examiner bears the initial burden of providing some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.

Because there is no rational underpinning provided to support modifying the teachings of the '852 patent to arrive at the claimed invention, no *prima facie* case of obviousness has been established. Applicants therefore respectfully request that the rejection be reconsidered and withdrawn.

3. Obviousness rejection based on Buechler, U.S. Patent 5,458,852, in view of Slovacek *et al.*, U.S. Patent 5,242,837

Applicants respectfully traverse the rejection of claims 95 and 117 as allegedly being unpatentable as obvious over Buechler *et al.*, U.S. Patent No. 5,458,852 ("the '852 patent") in view of Slovacek *et al.*, U.S. Patent 5,242,837 ("the '837 patent"). Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness.

This rejection fails for the same reasons discussed above. The entirety of the Examiner's obviousness analysis is that if the '852 patent does not anticipate the claimed invention, "[a]bsent evidence to the contrary the invention is alternatively considered obvious." Examiner's Answer, page 9. Applicants note that it is not the obligation of the applicant to provide evidence disproving obviousness in the absence of a *prima facie* showing. Rather, the Examiner bears the initial burden of providing some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.

The now-referenced '837 patent is cited only for the disclosure of "a fluorometer as a useful optical detector" (Examiner's Answer, page 10), and so does not cure the deficiencies noted for the primary '852 patent.

Because there is no rational underpinning provided to support modifying the teachings of the cited art to arrive at the claimed invention, no *prima facie* case of obviousness has been established. In view of the foregoing, Applicants respectfully request that the rejection be reconsidered and withdrawn.

4. Obviousness rejection based on Buechler, U.S. Patent 5,458,852, in view of Foster *et al.*, U.S. Patent 4,444,879

Applicants respectfully traverse the rejection of claims 28, 101, 102, 104, 107, 108, 128, and 128 as allegedly being unpatentable as obvious over Buechler *et al.*, U.S. Patent No. 5,458,852 ("the '852 patent") in view of Foster *et al.*, U.S. Patent 4,444,879 ("the '879 patent"). Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness.

This rejection fails for the same reasons discussed above. The entirety of the Examiner's obviousness analysis is that if the '852 patent does not anticipate the claimed invention, "[a]bsent evidence to the contrary the invention is alternatively considered obvious." Examiner's Answer, page 9. Applicants note that it is not the obligation of the applicant to provide evidence disproving obviousness in the absence of a *prima facie* showing. Rather, the Examiner bears the initial burden of providing some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.

As noted above, the '837 patent is cited only for the disclosure of "a fluorometer as a useful optical detector" (Examiner's Answer, page 11), and the '879 patent is cited only for the disclosure of assay reagents in kit form (Examiner's Answer, page 11), and so neither cited patent cures the deficiencies noted for the primary '852 patent.

Because there is no rational underpinning provided to support modifying the teachings of the cited art to arrive at the claimed invention, no *prima facie* case of obviousness has been established. In view of the foregoing, Applicants respectfully request that the rejection be reconsidered and withdrawn.

5. Obviousness rejection based on Buechler, U.S. Patent 5,458,852, in view of Slovacek *et al.*, U.S. Patent 5,242,837, and Foster *et al.*, U.S. Patent 4,444,879

Applicants respectfully traverse the rejection of claim 103 as allegedly being unpatentable as obvious over Buechler *et al.*, U.S. Patent No. 5,458,852 ("the '852 patent") in

view of both Slovacek *et al.*, U.S. Patent 5,242,837 ("the '837 patent") and Foster *et al.*, U.S. Patent 4,444,879 ("the '879 patent"). Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness.

This rejection fails for the same reasons discussed above. The entirety of the Examiner's obviousness analysis is that if the '852 patent does not anticipate the claimed invention, "[a]bsent evidence to the contrary the invention is alternatively considered obvious." Examiner's Answer, page 9. Applicants note that it is not the obligation of the applicant to provide evidence disproving obviousness in the absence of a *prima facie* showing. Rather, the Examiner bears the initial burden of providing some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.

The now-referenced '879 patent is cited only for the disclosure of assay reagents in kit form (Examiner's Answer, page 11), and so does not cure the deficiencies noted for the primary '852 patent.

Because there is no rational underpinning provided to support modifying the teachings of the cited art to arrive at the claimed invention, no *prima facie* case of obviousness has been established. In view of the foregoing, Applicants respectfully request that the rejection be reconsidered and withdrawn.

CONCLUSION

Applicants respectfully submit that the pending claims are in condition for allowance. An early notice to that effect is earnestly solicited. Should any matters remain outstanding, the Examiner is encouraged to contact the undersigned at the address and telephone number listed below so that they may be resolved without the need for additional action and response thereto.

Respectfully submitted,

Date 11/29/2007

By

FOLEY & LARDNER LLP
Customer Number: 30542
Telephone: (858) 847-6722
Facsimile: (858) 792-6773

Richard Warburg, Reg. No. 32,327
By Barry S. Wilson, Reg. No. 39,431
Attorney for Applicant